



Guidelines for Medical Necessity Determination for Ambulatory Infusion Pumps (Insulin Pumps)

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth needs to determine medical necessity for ambulatory infusion pumps (insulin pumps). These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 409.000 and 450.000, Subchapter 6 of the *Durable Medical Equipment Manual*, and the *MassHealth DME and Oxygen Payment and Coverage Guidelines Tool* for information about coverage, limitations, service conditions, and other prior-authorization (PA) requirements. Providers serving members enrolled in a MassHealth-contracted managed care organization (MCO) should refer to the MCO's medical policies for covered services.

MassHealth always requires prior authorization for ambulatory infusion pumps (insulin pumps). MassHealth reviews requests for prior authorization on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

Section I. General Information

An ambulatory infusion pump (insulin pump) is an externally worn device for the continuous or pulsed subcutaneous administration of insulin to diabetics who require insulin but who are either unable to self-administer medication or who require meticulous medication to minimize effects or complications of diabetes. It consists of an external battery-operated pump that carries the insulin beneath the skin. MassHealth considers approval for coverage of insulin pumps on an individual, case-by-case basis, in accordance with 130 CMR 409.000 and 450.204. MassHealth requires an initial three-month trial period for all insulin pumps. Prior authorization is required for use of the pump during the initial three-month trial period, and a separate prior authorization is required for continued use of the pump after successful completion of the initial three-month trial.

Section II. Clinical Guidelines

A. Clinical Coverage

MassHealth bases its determination of medical necessity for insulin pumps on clinical data including, but not limited to, indicators that would affect the relative risks and benefits of using the device. **MassHealth requires an initial three-month trial period in the use of the pump. For the three-month trial period the criteria include, but are not limited to, the following, as documented in the clinical record.**

1. The patient has a primary diagnosis of Type 1 or Type 2 diabetes, with additional diagnosis codes pertinent to any co-morbid conditions (e.g., retinopathy, nephropathy, or neuropathy), if applicable.
2. The patient is motivated to maintain optimal control of his or her diabetes.
3. The patient has the ability to operate and can use the insulin pump.
4. The patient has been performing multiple daily injections (MDIs) consisting of at least three injections per day with frequent self-adjustments of insulin doses for at least six months prior to insulin pump initiation.
5. The patient consistently performs at least four or more self-monitored blood glucose tests per day.
6. The patient demonstrates willingness to adhere to a proper diet and exercise regimen.
7. The most recent lab values indicate a glycosylated hemoglobin level (HbA1c) > 7.0 percent (exceptions can be made based on the unique features of individual cases).
8. Indications of at least one of the following factors are present.
 - a. The patient has a history of recurring hypoglycemia.
 - b. The patient has experienced fluctuations of more than 100 mg/dL in blood glucose before mealtime.
 - c. The patient has experienced dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL.
 - d. The patient has a history of severe glycemic excursions.
9. Prior treatments with MDIs were tried and were not effective in managing blood sugars and/or medical symptoms.

For continued use after the three-month trial these criteria include, but are not limited to, the following, as documented in the clinical record.

1. The patient continues to be motivated to maintain optimal control of diabetes.
2. The patient has demonstrated the ability to operate and can use the insulin pump to manage blood sugar.
3. The patient has successfully completed and demonstrated compliance with all aspects of the three-month trial and has not been noted to have any major adverse reactions or complications.
4. The patient consistently performs at least four or more self-monitored blood glucose tests per day.
5. The patient continues to demonstrate willingness to adhere to a proper diet and exercise regimen.
6. At the time of the PA request for continued use of the insulin pump, the HbA1c level has stabilized or improved.
7. At the time of the PA request for continued use of the insulin pump, there is clinical evidence demonstrating stabilization or improvement as follows (from what had been present and documented as part of the most recently approved PA request for an insulin pump for the patient) for at least one of the following indications.
 - a. The patient's recent history of recurring hypoglycemia has stabilized or improved.
 - b. The patient's fluctuations of more than 100 mg/dL in blood glucose before mealtime has stabilized or improved.
 - c. The patient's experience(s) of dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL has stabilized or improved.
 - d. The patient's history of severe glycemic excursions has stabilized or improved.
8. Continued coverage of an insulin pump requires that the member be seen and evaluated by the prescribing provider at least every three months, and that the prescribing provider work closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy.
9. Other pertinent clinical information about the patient may be requested by MassHealth.

B. Noncoverage

MassHealth pays providers only for medically necessary services (see 130 CMR 450.204). MassHealth does not consider insulin pumps to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following.

1. The patient has not engaged in an initial three-month trial phase.
2. The patient enrolled in an initial three-month trial and either failed or is not motivated and is not likely to benefit from another three-month trial.
3. The patient is unable to perform frequent blood glucose monitoring or is unable to technically operate an insulin pump because of behavioral, psychological, or other reasons.
4. The patient desires the insulin pump only for convenience purposes.

Section III. Submitting Clinical Documentation

All insulin pumps require prior authorization from MassHealth. Requests for prior authorization for insulin pumps must be accompanied by clinical documentation that supports the medical necessity for the insulin pump being requested and must be submitted to MassHealth in accordance with 130 CMR 409.418. As part of the PA request, the provider of durable medical equipment must obtain a written prescription and letter of medical necessity signed by the member's prescribing provider. The prescription and letter of medical necessity must meet the requirements of 130 CMR 409.416. The *MassHealth Prescription and Letter of Medical Necessity Review Form for Ambulatory Infusion (Insulin) Pumps* should be used for this purpose. Any additional clinical documentation supporting medical necessity must be submitted with the prior authorization request. Providers are strongly encouraged to submit PA requests electronically and all information pertinent to the request must be submitted using the Provider Online Service Center (POSC) or by completing a MassHealth Prior Authorization Request form (PA-1) and attaching the pertinent documentation. Questions about POSC access should be directed to the MassHealth Customer Service Center at 1-800-841-2900.

A. Documentation of medical necessity for the initial three-month trial period must include documentation of all of the following:

1. a primary diagnosis of Type 1 or Type 2 diabetes, with additional ICD codes pertinent to co-morbid conditions (e.g., retinopathy, nephropathy, or neuropathy);
2. patient motivation to maintain optimal control of diabetes;
3. patient ability to properly operate and use the insulin pump;
4. patient performance of multiple daily injections (MDIs) consisting of at least three injections per day with frequent self-adjustments of insulin doses for at least six months prior to insulin pump initiation;
5. consistent performance by patient of at least four or more self-monitored blood glucose tests per day;
6. patient demonstration of willingness to adhere to a diet and exercise regimen;
7. the most recent lab values indicating a glycosylated hemoglobin level (HbA1c) > 7.0 percent (exceptions can be made based on the unique features of individual cases);
8. indication of at least one of the following:
 - a. history of recurring hypoglycemia;
 - b. fluctuations of more than 100 mg/dL in blood glucose before mealtime;
 - c. dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; or
 - d. history of severe glycemic excursions; and
9. prior treatments with MDIs that have been tried and have not been effective in managing blood sugars and/or medical symptoms.

B. Documentation of medical necessity for continued use after the three-month trial must include documentation of all of the following:

1. continued patient motivation to maintain optimal control of diabetes;
 2. demonstration by patient of the ability to properly operate and use the insulin pump to manage blood sugar;
 3. successful completion and demonstrated compliance with all aspects of the three-month trial period with no noted major adverse reactions or complications;
 4. consistent performance by patient of at least four or more self-monitored blood glucose tests per day;
 5. demonstrated willingness by patient to adhere to a proper diet and exercise regimen;
 6. at the time of the PA request for continued use of the insulin pump, the HbA1c level has stabilized or improved;
 7. at the time of the PA request for continued use of the insulin pump, clinical evidence demonstrating stabilization or improvement of at least one of the following indications:
 - a. history of recurring hypoglycemia;
 - b. fluctuations of more than 100 mg/dL in blood glucose before mealtime;
 - c. dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; or
 - d. history of severe glycemic excursions;
 8. patient is being seen and evaluated by a prescribing provider at least every three months and follow up care is being rendered by a prescribing provider who works closely with a team including nurses, diabetic educators and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy; and
 9. other pertinent clinical information that MassHealth may request.
- C. A new prior authorization request for insulin pumps must be submitted to continue the use of the pump(s) before the expiration of any current prior authorization.


Select References

1. Bode B, Steed R, Davidson P. Reduction in severe hypoglycemia with long-term continuous subcutaneous insulin infusion in type 1 diabetes. *Diabetes Care*. 1996; 19: 324-327.
2. DeVries J, Snoek F, Kostense P, et al. A randomized trial of continuous subcutaneous insulin infusion and intensive injection therapy in type 1 diabetes patients with long-standing poor glycemic control. *Diabetes Care*. 2002; 25 (11): 2074-2080.
3. Simmons D, Thompson C, Scott D. Use of insulin pump in pregnancies complicated by type 2 diabetes and gestational diabetes in a multiethnic community. *Diabetes Care*. 24: 2078-2082, 2001.
4. Bergenstal RM, Tamborlane WV, Ahmann A, Buse JB, Dailey G, Davis SN, Joyce C, Peoples T, Perkins BA, Welsh JB, Willi SM, Wood MA for the STAR 3 Study Group. Effectiveness of Sensor-Augmented Insulin-Pump Therapy in Type 1 Diabetes. *New England Journal of Medicine*. 2010; 363: 311-320.

These Guidelines are based on review of the medical literature and current practice in the use of ambulatory infusion pumps (insulin pumps). MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of proposed treatment. Some language used in this communication may be unfamiliar to other readers; in this case, contact your health-care provider for guidance or explanation.

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Approved by: , Medical Director